UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
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Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/528,989	03/20/00	VOGEL J	9676-292

020582
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HM22/0924

EXAMINER	
WELLS I	
ART UNIT	**PAPER NUMBER**
1619	12

DATE MAILED: 09/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application N .	Applicant(s)	
	09/528,989	VOGEL ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1619	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-51 are currently pending.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed August 27, 2001 (Paper No. 11) to the rejection of claims 1-51 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive. The rejection of claims 1-51 made by the Examiner under 35 USC 112, 102 and the judicially created doctrine of obviousness-type double patenting has been fully considered and deemed persuasive. Therefore, the said rejections are hereby withdrawn.

103 Rejection Maintained

The rejection of claims 1-51 under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. or Rhee et al. in view of Boshchetti et al., Tomoko, and Vacanti is MAINTAINED for the reasons set forth in the Office Action mailed April 27, 2001, Paper No. 9, and those found below.

Applicant argues that Rhee teaches away from the claimed invention and that "what Rhee discloses is a method in which no solid implant material. . .is present in the composition". This argument is not persuasive. First, the instant invention and that of Rhee are both drawn to compositions for tissue bulking comprising biocompatible, hydrophilic polymers. Second, the independent claims of the instant invention do not recite a solid implant material as a limitation, thus this argument is not commensurate in scope with the claims of the instant invention.

Applicant argues that Hubbard teaches away from the claimed invention "by its disclosure of a biocompatible composition made from ceramic particles. . .and a method of soft tissue augmentation comprising forming such ceramic particles by spray-drying. . .and agitating or rolling the globular particles". First, the instant invention and that of Hubbard are both drawn

to compositions for tissue bulking comprising spherical particles of biocompatible material. Second, the independent claims of the instant invention are not directed toward a method of making microspheres, thus this argument is not commensurate in scope with the claims of the instant invention.

Applicant argues that "Boschetti actually teaches away from the claimed invention through its disclosure that the microspheres be used as emboli for therapeutic vascular occlusion as opposed to their use in tissue bulking". This argument is not persuasive. The Examiner respectfully refers Applicants to their definition of tissue bulking on pg. 11 of the specification. The Examiner respectfully points out that vascular lumens comprise non-dermal tissues.

Applicant argues that "Hori, like Boschetti, teaches away from the claimed invention through its disclosure that granules of a water-absorbing resin be used as emboli in occlusions or embolizations in blood vessels". This argument is not persuasive. Again, the Examiner respectfully refers Applicants to their definition of tissue bulking.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

DAMERON L. JONES
PRIMARY EXAMINER

lqw
September 7, 2001